

REMARKS

The above amendment with the following remarks is submitted to be fully responsive to the Official Action of October 03, 2003. Reconsideration of this application in light of the amendment and the allowance of this application are respectfully requested.

Initially, it is noted that, by the amendment, the specification has been replaced with a Second Substitute Specification submitted herewith which includes various amendments to the first substitute specification so as to clarify the present invention and overcome the objections and rejections as described herein below. The Second Substitute Specification contains no new matter and a mark-up copy of the specification showing the changes made is also appended. New Figures 1-7 are also submitted herewith to replace original Figures 1-9. It is respectfully requested the new Figures 1-7 be substituted for Figures 1-9. No new matter has been added.

The drawings stand objected to under 37 C.F.R. §1.83(a) as failing to include every feature of the present invention and, specifically, the external proximal valve recited in the claims. In response, the external proximal valve is now shown in new Figure 7 along with only the original features of the present invention described in the original specification and shown in the original drawings. This figure is not only supported by original claim 9 but also by the specification which suggests that the self sealing valves may be equally used as external proximal valves or as internal distal valves. Therefore, it is respectfully requested that this rejection has been overcome.

Claims 3-5 stand rejected under 35 U.S.C. §112, first paragraph. Specifically, the Examiner asserted that the description of the cuff valve 8, especially with respect to the "actuates" and the reference to "a distal tube", is so unclear that it would not enable one skilled in the art to make and/or use the invention. In response, the specification has been amended to delete the reference to the cuff valve and the actuates and, instead, focus on the description of the self

sealing valves used in place of the cuff valve as specifically taught by the original specification. Also, the reference to "a distal tube" has been deleted. It is believed that these amendments effectively clarify the description of the present invention as originally taught in the specification so as to enable a person of ordinary skill in the art to make and/or use the invention. Therefore, it is respectfully requested that this rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 3-5, 10, 11 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, claims 3-5, 10, 11 and 12 have been either amended or cancelled to correct the deficiencies noted by the Examiner. Thus, it is respectfully requested that the present invention has been overcome.

It should also be noted that the Examiner asserted that the sleeve is not removable from the body cavity engagement means and the fixing means. Applicants' representative respectfully points out that although the original specification may not explicitly teach the removability of the sleeve, the specification also does not specifically exclude the claimed invention from including a removable sleeve since the specification nowhere suggests that the sleeve is not removable from the body cavity engagement means and the fixing means. Thus, it is Applicants' contention that the claims, even including the word "connected", would still cover a device having a sleeve that is connected, albeit removable, from the body cavity engagement means and the fixing means.

Claims 1-12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Golub et al. In response, independent claims 1, 11, and 12 have been amended to clarify the present invention. As a result, for the reasons described herein below, it is respectfully requested that amended independent claims 1, 11, and 12 are not obvious in view of Golub et al.

Golub et al. does not render obvious the present invention as recited in newly amended independent claims 1, 11 and 12 for the following reasons. Golub et al. admittedly discloses an access device for endoscopic surgery which includes a proximal plate, a distal plate, an elongated flexible sleeve extended between the

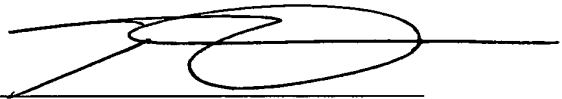
first and second plates, a proximal seal member and adjustment members. However, the adjustment members are merely used to adjust the position of the second plate by pulling the second plate into engagement with the abdominal wall. The amended independent claims 1, 11 and 12 each require the combination of a sealing means, or one of an external proximal sealing valve and an internal proximal sealing valve, in combination with a sleeve that applies outward pressure against a patient's body sufficient to retract the sides of an incision to define an access port. Specifically, claim 1 requires the positioning of proximal ring to retract the sleeve which in turn applies outward pressure to retract the incision, whereas claim 11 requires one of an external proximal sealing valve and an internal distal sealing valve in combination with a sleeve having an adjustable length that shortens to cause the sleeve to apply outward pressure to retract an incision. Claim 12 requires the combination of one of an external proximal sealing valve and an internal distal sealing valve in combination with an adjustment means for adjusting the length of the sleeve to cause the sleeve to apply outward pressure against the patient's body sufficient to retract the sides of the incision. Golub et al. nowhere suggests or discloses any means whatsoever for retracting the incision and certainly nowhere discloses nor remotely suggests that the Golub et al. sleeve could apply outward pressure against the patient's body, much less sufficient pressure to retract the incision. Though retractors may be well known in the art, no prior art of record including Golub et al. suggest the combination of a sleeve for applying outward pressure against a patient's body sufficient to retract sides of an incision and one of an external proximal sealing valve and an internal distal sealing valve to prevent substantial leakage of gas from the body cavity on inflation when in an operative position and formed to mold about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. Therefore, Golub et al. does not render the present invention as recited in amend independent claims 1, 11 and 12 obvious.

Accordingly, reconsideration and withdrawal of the rejection of independent claims 1, 11 and 12 under 35 U.S.C. §103(a) is respectfully requested. Likewise, dependent claims 2-4 and 7-10 are allowable in that they depend from allowable base claim 1. New dependent claims 13-18 are added to more fully cover the present invention.

The amendments to the specification and claims are made merely to clarify the present invention. No new matter has been added by the amendments.

In view of the foregoing, it is submitted that the present application is in condition for allowance and a notice to that effect is respectfully requested. However, if the Examiner deems that any issue remains after considering this response, he is invited to call the undersigned to expedite the prosecution and work out any such issue by telephone.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Tim L. Brackett, Jr.', written over a horizontal line.

Tim L. Brackett, Jr.
Registration No. 36,092

NIXON PEABODY LLP
401 9th Street, N.W., Suite 900
Washington, D.C. 20004-2128
(202) 585-8000
(202) 585-8080 (Fax)

Date: April 1, 2004